

NORTH CAROLINA
IREDELL COUNTY

FILED
IN THE GENERAL COURT OF JUSTICE
SUPERIOR COURT DIVISION
2021 OCT -8 PM 3:10 No. 21CVS 2797

AURELIA SHERRILL and BELVIN
SHERRILL,

Plaintiffs,

v.

AZIYO BIOLOGICS, INC.,
MEDTRONIC, PLC, MEDTRONIC
USA, INC., and MEDTRONIC, INC.,

Defendants.

COMPLAINT

Plaintiffs, Aurelia Sherrill and Belvin Sherrill, by and through their attorneys, and for their complaint against Defendants, Aziyo Biologics, Inc. ("Aziyo"), Medtronic, PLC, Medtronic USA, Inc., and Medtronic, Inc. (collectively "Medtronic") allege as follows:

I. INTRODUCTION

1. This action seeks to recover damages for the personal injuries suffered by Ms. Sherrill as the direct and proximate result of the wrongful conduct of Defendants in connection with the research, testing, design, development, manufacture, production, inspection, labeling, advertisement, marketing, promotion, sale, and distribution of a product known as FiberCel Fiber Viable Bone Matrix ("FiberCel"). Defendants' negligence resulted in personal injury suffered by the Plaintiff after the FiberCel product was used in an implant procedure. Her spouse, Mr. Sherrill, alleges a claim for loss of consortium.

II. PARTIES

2. Plaintiffs Mrs. Sherrill and Mr. Sherrill have been and are residents of the State of North Carolina, residing in Statesville, North Carolina.

3. Defendant Aziyo is a Delaware corporation, whose registered agent for service of process is Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808. Aziyo's principal place of business is located at 12510 Prosperity Drive, Suite 370, Silver Springs, Maryland 20904. Aziyo does business throughout the United States, including conducting regular business in North Carolina.

4. Aziyo sells a variety of medical products, including implantable electronic devices, orthopedic and spinal repair products, and soft tissue reconstruction products.

5. Upon information and belief, Aziyo developed, manufactured, marketed, promoted, distributed and supplied the FiberCel product which was implanted into Plaintiff and caused her personal injury.

6. Defendant Medtronic, PLC is incorporated in Ireland, having its principal place of business at 20 Lower Hatch Street, Dublin, 2, Ireland. Its United States operational headquarters are located at 710 Medtronic Parkway, Minneapolis, MN 55432-5604, and its registered agent is Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808. Medtronic, PLC is the parent company of Medtronic, Inc. Medtronic, PLC does business throughout the United States, including conducting regular business in North Carolina.

7. Defendant Medtronic USA, Inc. is incorporated under Minnesota law, having its principal place of business at 710 Medtronic Parkway, Minneapolis, MN 55432-5604 and its registered agent is Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware

19808. Medtronic USA, Inc. does business throughout the United States, including conducting regular business in North Carolina.

8. Defendant Medtronic, Inc. is incorporated in Minnesota, having its principal place of business at 710 Medtronic Parkway, Minneapolis, MN 554325604 USA. It has a registered agent for service, Corporation Service Company, with an address of 251 Little Falls Drive, Wilmington, Delaware 19808. It also has a North Carolina registered agent, Corporation Service Company, with an address of 2626 Glenwood Avenue, Suite 550, Raleigh NC 27608. Medtronic, Inc. does business throughout the United States, including in North Carolina.

9. Medtronic develops therapeutic and diagnostic medical products, and is among the world's largest medical technology, services, and solutions companies. On information and belief, all three of the above-referenced Medtronic entities were directly and pertinently involved in the marketing, sale and distribution of the FiberCel product and are jointly and severally liable.

10. Upon information and belief, during the pertinent times, Medtronic was designated as the exclusive U.S. distributor of the FiberCel product manufactured by Defendant Aziyo.

11. At all times relevant, Medtronic distributed, supplied and sold the FiberCel product which was implanted into Plaintiff, and which is the subject of this complaint.

12. Defendants, at all times relevant to this lawsuit, manufactured, developed, designed, marketed, distributed, promoted, supplied and/or otherwise sold (directly or indirectly) FiberCel to various locations for use in surgeries requiring bone grafting, including to Iredell Memorial Hospital, where contaminated FiberCel was surgically implanted into Plaintiff Sherrill, causing her to suffer harm as described herein.

III. JURISDICTION AND VENUE

13. This Court has jurisdiction over the parties as they have all had substantial contacts with the State of North Carolina and otherwise meet the criteria for personal jurisdiction.

14. The Court has jurisdiction over the subject matter, in that these are state law claims and the amount in controversy exceeds the sum of \$25,000, exclusive of interest and costs.

15. At all times relevant to this action, the Defendants have been engaged, either directly or indirectly, in the business of manufacturing, marketing, selling, promoting and/or distributing FiberCel to various locations for use in surgeries requiring bone grafting within the State of North Carolina, with a reasonable expectation that the product would be used or consumed in this state, and have regularly solicited or transacted business in this State, thereby subjecting the Defendants to personal jurisdiction.

16. Venue is proper in this Court.

IV. FACTUAL ALLEGATIONS

A. FiberCel Fiber Viable Bone Matrix.

17. FiberCel Fiber Viable Bone Matrix is made from human tissue consisting of cancellous bone particles with preserved living cells, combined with demineralized cortical fiber. It is engineered to be like natural tissue and is used as a bone void filler in various orthopedic and spinal procedures. The allografts contain the scaffold, growth factors and cells required for regeneration critical for successful bone formation.

18. FiberCel is marketed for use in orthopedic and reconstructive bone grafting procedures with the use of autologous bone or other forms of allograft bone or alone as a bone graft. FiberCel is made with donor tissue and growth factor cells.

19. Because FiberCel uses human tissue from human donors, and includes preserved living cells, it is imperative that rigorous screening and quality control procedures be used to ensure that the resultant product is not contaminated. This is also so because the FiberCel product is meant to be used in surgeries and medical procedures involving patients already in a vulnerable medical status given their context as procedure recipients.

20. On June 20, 2019, Aziyo announced it had signed an exclusive, multiyear distribution agreement with Defendant Medtronic in the U.S. orthopedic market. According to the agreement, Aziyo agreed to manufacture and supply FiberCel to Medtronic for distribution through the company's sales and marketing organization.

21. Medtronic is a very large and sophisticated medical manufacturer and distributor. It holds itself out as having special knowledge and expertise regarding the medical products that it carries and distributes, and in fact even has training and instructional videos pertaining to the use of the FiberCel product on its Medtronic English language website.

B. The FiberCel Product is Recalled.

22. On June 2, 2021, the United States Food & Drug Administration ("FDA") issued an urgent voluntary recall of FiberCel, specifically three products from Donor Lot Number NMDS210011: VMB9901, VBM9905, and VBM9910.

23. Aziyo initiated the voluntary recall in response to reports of patients testing positive for Tuberculosis and post-surgical infections following the surgical implantation of FiberCel as part of an orthopedic or spinal procedure.

24. Tuberculosis ("TB") is an infectious disease caused by bacteria known as *Mycobacterium tuberculosis*. TB is highly contagious, and mostly impacts the lungs, but can also spread through the lymph nodes to other parts of the body, including the kidneys, brain, and spine.

25. Once mycobacterium tuberculosis is introduced to the body, the bacteria must then proliferate within the new host for the host to develop disease. When this bacterium is introduced in a surgical wound, the patient is already in an immunocompromised position, causing them to have an increased likelihood of developing TB, which can be fatal.

26. The recalled contaminated FiberCel units delivered to 20 states.

27. Defendant Aziyo has acknowledged that at least one hospital reported post-surgical infections in seven of twenty-three patients that received FiberCel from Donor Lot No. NMDS210011. At least four patients that have received FiberCel from this Donor Lot have tested positive for Tuberculosis, including Plaintiff.

28. In a press release dated June 7, 2021, Aziyo acknowledged

learning of post-surgical infections in patients treated with FiberCel, including some patients that tested positive for tuberculosis. The lot consists of 154 units of FiberCel, all derived from a single donor, that were shipped to facilities in 20 states. Aziyo is investigating the source of the infections in coordination with its distributor, the U.S. Food and Drug Administration and the U.S. Centers for Disease Control and Prevention. The Company is in the process of recovering the unused units from this lot....

29. The product recall acknowledged that viruses and bacteria, including Tuberculosis, can be transplanted into patients along with the FiberCel product.

C. Plaintiff Received the Contaminated FiberCel and Suffered Severe Injury.

30. Plaintiff Mrs. Sherrill underwent spinal surgery on April 6, 2021, at Iredell Memorial Hospital in Statesville, North Carolina.

31. The surgery was performed by Dr. Peter Miller, M.D., a neurosurgeon certified by the American Board of Neurological Surgery, at Iredell Memorial Hospital in Statesville.

32. During Plaintiff's surgery, Dr. Miller implanted the FiberCel product, Lot Number NMDS210011, into Mrs. Sherrill's body.

33. The FiberCel product contained no adequate warning to Dr. Miller or to Plaintiff of the danger that she could contract tuberculosis if a FiberCel product was used during the surgery.

34. Unbeknownst to Plaintiff or her physicians at the time of her surgery, the FiberCel implanted into Plaintiff was contaminated with tuberculosis.

35. While the surgery was initially a success, Plaintiff soon began experiencing lower back pain and spasms about three weeks after her surgery.

36. On June 7, 2021, Plaintiff's physicians notified Plaintiff she may have been exposed to TB from the FiberCel that was implanted during her surgery. Plaintiff subsequently tested positive for TB.

37. Plaintiff's tuberculosis was caused by the contaminated and recalled FiberCel used in her operation.

38. As a direct and proximate result of the implantation of contaminated FiberCel, Plaintiff is forced to undergo a grueling medical protocol to manage her TB diagnosis.

39. Plaintiff will require continued medical monitoring now and into the future in order to monitor Plaintiff's health related to the ongoing and serious nature of her tuberculosis diagnosis.

40. Plaintiff would not have suffered from tuberculosis had Defendants sold and distributed a product that was free from tuberculosis contamination.

41. Plaintiff further has experienced significant side effects from the extensive treatments causing a cascade of sequential complications caused by the contaminated FiberCel product.

42. As a direct and proximate result of Plaintiff's exposure to Defendants' contaminated FiberCel product used in her spinal surgery, Plaintiff has suffered and continues to suffer from pain and discomfort, severe emotional distress, the loss of daily functions, and

economic loss, including, but not limited to, present and future medical expenses, lost earnings, and future lost earning capacity, all as a direct result of Defendants' liability producing conduct.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION
NEGLIGENCE

43. Plaintiff incorporates the foregoing paragraphs 1 through 42 as though the same were set forth at length herein.

44. Defendants owed a duty to Plaintiff Mrs. Sherrill to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality, assurance, quality control, and distribution of FiberCel into the stream of commerce, including a duty to assure that the FiberCel would not cause those who used it, including Plaintiff, to suffer adverse harmful effects.

45. Defendants failed to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control and distribution of FiberCel.

46. Defendants knew or should have known that those individuals who used the defective FiberCel were at risk for suffering harmful effects from it, including but not limited to, tuberculosis, as well as other severe injuries which are permanent and lasting in nature, physical pain, mental anguish, and diminished enjoyment of life.

47. Defendants were negligent in designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing, and sale of FiberCel. The negligence of Defendants, their agents, servants, and employees, included, but was not limited to, the following acts and/or omissions:

- a. Designing manufacturing, producing, creating, and/or promoting FiberCel without adequately, sufficiently, or thoroughly testing the FiberCel units to ensure they were free from contamination of communicable diseases, including but not limited to, tuberculosis;
- b. Not conducting a sufficient quality control testing program to determine whether or not the subject FiberCel was manufactured properly and was free from contamination or other defects making it unsafe for users of the product;
- c. Failing to adequately and properly obtain and review complete donor medical history with regard to the product;
- d. Negligently failing to timely recall their dangerous and defective FiberCel lots at the earliest date that it became known that certain lots of FiberCel were, in fact, dangerous and defective;
- e. Negligently manufacturing FiberCel in a manner that was dangerous to those individuals who had FiberCel implanted into their bodies;
- f. Negligently producing FiberCel in a manner that was dangerous to those individuals who had it transplanted into their bodies;
- g. Failing to warn individuals who were using the product of the risks of contracting tuberculosis; and
- h. Acting otherwise careless and negligently.

48. Defendants knew or should have known that consumers such as Plaintiff would suffer foreseeable injury and be at increased risk of suffering an injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

49. Defendants' negligence was the proximate cause of and was a substantial factor in causing Plaintiff's physical, mental, emotional injuries and harm, and economic loss.

50. Pursuant to N.C.G.S. § 99B-5, each of the Defendant manufacturers and sellers herein acted unreasonably in failing to provide such warning or instruction, and their failure to provide adequate warning or instruction was a proximate cause of the harm for which damages are sought.

51. At the time the product left the control of the manufacturer or seller, the product, without an adequate warning or instruction, created an unreasonably dangerous condition that the manufacturer or seller knew, or in the exercise of ordinary care should have known, posed a substantial risk of harm to a reasonably foreseeable claimant.

52. After the product left the control of the manufacturer or seller, the Defendants as manufacturers or sellers became aware of or in the exercise of ordinary care should have known that the product posed a substantial risk of harm to a reasonably foreseeable user or consumer. However, Defendants failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances.

53. By reason of the foregoing, Defendants are liable to Plaintiff for all of her injuries, harm, damages, and economic and non-economic losses in an amount to be determined in the future in excess of \$25,000.

SECOND CAUSE OF ACTION
DEFECTIVE DESIGN

54. Plaintiff incorporates the foregoing paragraphs 1 through 53 as though the same were set forth at length herein.

55. At all times material to this lawsuit, Defendants were engaged in the business of designing, manufacturing, testing, marketing, distributing, and/or selling FiberCel for the sale to, and use by, members of the public.

56. Defendants manufactured, distributed, and/or sold the FiberCel product which was implanted into Plaintiff's body during her spinal surgery.

57. The FiberCel manufactured by Defendants reached Plaintiff without substantial change in its condition when it was implanted into her spine during her operation.

58. The FiberCel was defective and unreasonably dangerous when it entered into the stream of commerce and when used by Plaintiff.

59. Pursuant to N.C.G.S. § 99B-6, at the time of its manufacture, the manufacturer acted unreasonably in designing or formulating the product, that this conduct was a proximate cause of the harm for which damages are sought, and at the time the product left the control of the manufacturer, the manufacturer unreasonably failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design or formulation that could then have been reasonably adopted and that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product.

60. At the time the product left the control of the manufacturer, the design or formulation of the product was so unreasonable that a reasonable person, aware of the relevant facts, would not use or consume a product of this design.

61. Under the circumstances Defendants' conduct was negligent with regard to the design of the product in that Defendants' lack of adequate quality control systems allowed the product to reach the injured claimant as occurred; and in considering:

- a. The nature and magnitude of the risks of harm associated with the design or formulation in light of the intended and reasonably foreseeable uses, modifications, or alterations of the product;
- b. The likely awareness of product users, whether based on warnings, general knowledge, or otherwise, of those risks of harm;
- c. The extent to which the design or formulation conformed to any applicable government standard that was in effect when the product left the control of its manufacturer;
- d. The utility of the product, including the performance, safety, and other advantages associated with that design or formulation;
- e. The technical, economic, and practical feasibility of using an alternative design or formulation at the time of manufacture; and

- f. The nature and magnitude of any foreseeable risks associated with the alternative design or formulation.

62. Defendants owe a duty to the general public, specifically to Plaintiff, to exercise reasonable care in the design, study, development, manufacture, promotion, sale, marketing, and distribution of FiberCel. Defendants failed to exercise reasonable care in the design of FiberCel because, as designed, FiberCel was capable of causing serious personal injuries such as those suffered by Plaintiff during the foreseeable use of FiberCel.

63. The FiberCel implanted into Plaintiff was defective and, because of its defects, was unreasonably dangerous to persons who might reasonably be expected to require its use. In addition, this product was dangerous to the extent beyond that which could reasonably be contemplated by Plaintiff.

64. The FiberCel implanted into Plaintiff was defective at the time it was distributed by the Defendants or left their control.

65. Plaintiff was a person who would reasonably be expected to use FiberCel.

66. Defendants' failure to exercise reasonable care in the design, marketing, selling, distributing, and manufacturing of FiberCel was a proximate cause of Plaintiff's injuries and damages.

67. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Plaintiff was exposed to FiberCel, and suffered the injuries and damages set forth hereinabove and was damaged in an amount in excess of \$25,000.

THIRD CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

68. Plaintiff incorporates the foregoing paragraphs 1 through 67 as though the same were set forth at length herein.

69. Defendants are in the business of designing, manufacturing, supplying, selling, and placing into the stream of commerce certain goods, including FiberCel. By placing FiberCel into the stream of commerce, Defendants impliedly warranted that it was merchantable and fit and safe for its intended use.

70. A warranty that the goods were merchantable was implied in all relevant contracts for the sale of the instant product, and furthermore, any Defendant sellers were merchants with respect to goods of that kind. N.C.G.S. § 25-2-314.

82. The FiberCel manufactured and/or sold and was placed into the stream of commerce by Defendants and implanted into Plaintiff was contaminated, leading persons who received FiberCel implants to develop tuberculosis, including Plaintiff, and accordingly, was not fit, safe, or merchantable for its intended use.

83. The contamination in the FiberCel, manufactured, supplied, and placed into the stream of commerce by Defendants was present at the time the FiberCel units left Defendants' control and at the time it was implanted into Plaintiff as part of her spinal operation.

84. Defendants breached the implied warranty for FiberCel because it was contaminated, unmerchantable, and not fit for its intended purpose, resulting in personal injuries suffered by Plaintiff, including her development of tuberculosis.

85. Plaintiff was a foreseeable user of the FiberCel designed, manufactured, and placed into the stream of commerce by Defendants.

86. By reason of the foregoing, Defendants are liable to Plaintiff for her injuries, harm, damages, and economic and non-economic losses in an amount in excess of \$25,000 to be determined at trial.

FOURTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

87. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs 1 through 86 of this Complaint as if they were set forth at length herein.

88. At all times mentioned, Defendants expressly represented and warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendants and their authorized agents or sales representatives, orally and in publications, package inserts, and other written materials intended for physicians, medical patients, and the public, that FiberCel is safe, effective, fit, and proper for its intended use. Plaintiff and Plaintiff's physicians utilized FiberCel relying upon these warranties.

89. Defendants' own promotional materials and information states that FiberCel is processed in sterile conditions and is screened for bacteria and communicable disease.

90. In utilizing FiberCel, Plaintiff relied on the skill, judgment, representation, and foregoing express warranties of the Defendants. These warranties and representations were false in that FiberCel is unsafe and unfit for its intended uses.

91. As a result of the abovementioned breach of express warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein in excess of \$25,000.

FIFTH CAUSE OF ACTION
LOSS OF CONSORTIUM

92. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs 1 through 91 of this Complaint as if they were set forth at length herein.

93. During the pertinent time, the negligence of the Defendants proximately caused Plaintiff Mr. Sherrill to lose the consortium of his spouse, the Plaintiff Mrs. Sherrill.

94. Mr. and Mrs. Sherrill were legally married at the time of Plaintiff Mrs. Sherrill's above-alleged injury.

95. During the pertinent times, the claimant's marital relationship with his spouse had beneficial aspects including but not limited to marital services, society, affection and companionship.

96. As a direct and proximate result of Defendants' negligence, for a significant period of time Plaintiff Mr. Sherrill has lost the consortium of his spouse. There has been a disruption of marital services, society and companionship.

97. Defendants' negligence was a substantial factor in causing the loss of consortium.

98. Accordingly, Defendants should be jointly and severally found liable to the Plaintiff Mr. Sherrill in amount of damages as may be found by a jury at trial herein.

SIXTH CAUSE OF ACTION
PUNITIVE DAMAGES

99. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs 1 through 98 of this Complaint as if they were set forth at length herein.

100. Plaintiff is further informed and believes that Defendants' misconduct, as previously outlined herein, constituted a conscious disregard for the rights and safety of other persons, including Plaintiff, that had a great probability of causing substantial harm including, but not limited to, exposing Plaintiff and other recipients of FiberCel to tuberculosis, a potentially deadly infectious disease.

101. Plaintiff is further informed and believes that Defendants engaged in conduct with respect to the contaminated FiberCel unit alleged herein which was a legal cause of loss, damages, injuries, and harm to Plaintiff, and which exposed Plaintiff and other recipients of the contaminated

FiberCel units to serious complications, including the diagnosis of tuberculosis in Plaintiff's post-surgical wound.

102. Defendants' actions and inactions leading to the contamination of the FiberCel product were outrageous, willful and wanton, and done with reckless disregard for the safety of the Plaintiff.

103. Under the circumstances, Defendants' conduct gave rise to an aggravating factor for purposes of the North Carolina punitive damages statute, N.C.G.S. § 1D-1 *et seq.*

104. The Defendants' outrageous, willful and wanton, and reckless conduct in disregard of the safety of the Plaintiff was the direct proximate cause of Plaintiff's injuries and damages.

105. As a direct and proximate result of the Defendants' outrageous, willful and wanton, and reckless conduct in disregard of the safety of the Plaintiff, the Plaintiff has suffered and continues to suffer damages as set forth above.

106. Defendants thereby acted with a conscious disregard for the rights and safety of Plaintiff and other users of the contaminated FiberCel units, thus warranting an award of punitive damages to Plaintiff.

107. As a result of the willful, wanton or reckless conduct by Defendants giving rise to an aggravating factor under Chapter 1D, and to the extent the evidence may show, Plaintiff is entitled to an award of punitive damages to punish and deter.

JURY DEMAND

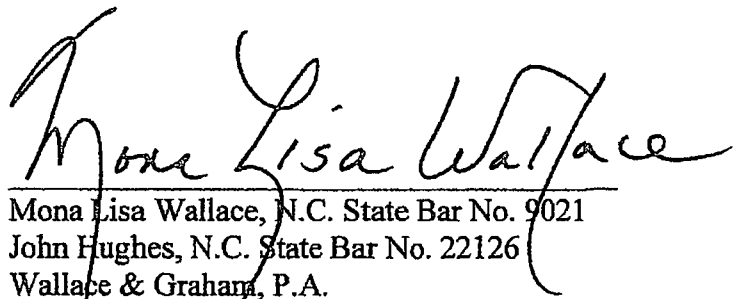
Plaintiff requests a trial by jury of all claims herein so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief against Defendants, jointly and severally, as follows:

- a. Compensatory damages exclusive of interest and costs, and in an amount to fully compensate Plaintiff for all past, present, and future pain, and suffering.
- b. Special damages, exclusive of interest and costs, and in an amount to fully compensate Plaintiff for all of her injuries and damages, both past and present;
- c. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;
- d. An award of damages for loss of consortium;
- e. To the extent the law may allow same, an award of expenses, and costs of this action, as well as any attorney fees that may be applicable;
- f. Pre-judgment and post-judgment interest in the maximum amount allowed by law;
and
- g. Such further relief as this Court deems necessary, just, and proper.

Respectfully submitted this the 7 day of October, 2021.



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